Approval: Original Signed by Mark Arenaz Date: 12/18/01
Manager, National Spent Nuclear Fuel Program

Approval: Original Signed by Robert Blyth Date: 12/18/01
NSNFP Quality Assurance Program Manager

I. PURPOSE AND SCOPE

This procedure establishes the process and responsibilities of the National Spent Nuclear Fuel Program (NSNFP) for corrective action management as applied to conditions adverse to quality identified in the NSNFP, NSNFP suppliers, and U.S. Department of Energy (DOE) spent nuclear fuel sites. This procedure may be applied to tracking deficiencies in other programs as requested by the NSNFP Quality Assurance Program Manager (QAPM).

II. SUMMARY

This procedure describes the following corrective action process.

A. Identification of conditions adverse to quality

B. Initiation of a deficiency report (DR) or corrective action request (CAR)

C. DR/CAR distribution and requesting responses

D. Items corrected during an audit or surveillance

E. DR/CAR response, extent of condition, remedial action, and action to prevent recurrence

F. Evaluation of responses to DRs and CARs

G. Delinquency identification and actions

H. Corrective Action Tracking Trending System (CATTS).

All time-line requirements and due dates identified in this procedure are associated with the administrative management of the corrective action process. Failures to meet these dates are managed as identified herein and are not considered a QA program violation.

III. PROCEDURE

A. Identifying Conditions Adverse To Quality

NSNFP Personnel

1. Report all potential or identified conditions adverse to quality to the NSNFP Quality Assurance Staff Manager (QASM).

QASM 2. For potential conditions adverse to quality identified through nonassessment activities, assign a NSNFP lead auditor (LA) to verify and document the condition.

LA 3. Evaluate the condition against the definition of a condition adverse to quality.

a. When a condition identified during nonassessment activities is determined not to be a condition adverse to quality, write a memorandum documenting the condition and a justification of why the condition is not adverse to quality.

b. Obtain a concurrence signature of the QASM.

(1) If the QASM provides concurrence, request the identifier of the condition to concur with the determination.

(2) If the QASM does not agree with the justification or if the condition is determined to be valid, GO TO Subsection B of this procedure.

c. If NSNFP personnel dispute a determination that there is not a condition adverse to quality, process a resolution in accordance with PMP 1.03, "Resolution of Quality Disputes."

LA/Auditor 4. Document conditions adverse to quality identified by audit or surveillance according to Subsection B of this procedure.

B. Initiating a Deficiency Report or Corrective Action Request

QAPM 1. When external oversight organizations request limited action or make recommendations, evaluate the condition requiring action or recommendation and determine whether implementation of this procedure is appropriate. If yes, implement the requirements of this procedure in response to requested actions or recommendations.

QASM 2. For conditions adverse to quality identified by external organizations, assign QA staff to document the deficiency in CATTS.

LA/Auditor 3. For all conditions adverse to quality, evaluate the condition for significance. A condition adverse to quality is significant when, if uncorrected, could have a serious effect on safety or the ability to isolate waste. Use the following criteria to determine if a condition is considered significant:

- A condition determined to be repetitive in nature that could impact SNF acceptance activities by DOE/RW
- A condition indicating a QA program breakdown

LA/Auditor

- A condition that, were it to remain uncorrected, could have an adverse impact on the ability to meet SNF acceptance criteria of DOE/RW-Waste Acceptance Systems Requirements Document (WASRD)
- A condition that could result in invalid or indeterminate SNF qualification data
- A condition that could result in invalid or indeterminate SNF records.

4. Complete Part I of the DR/CAR form in accordance with Form 16.02-1, DR/CAR Form Instructions.

5. Download an electronic copy of the DR/CAR form from the NSNFP web site. Document the deficiency in the CATTS database.

6. After the appropriate fields and sections are completed, print name, sign, and date Block 12.

7. Forward the signed DR/CAR to the QAPM for review and approval signature.

QAPM 8. Review the DR/CAR and return any comments to the LA.

LA 9. Incorporate comments from the QAPM and resubmit the DR/CAR to the QAPM for approval.

QAPM 10. If the DR/CAR is acceptable, print name, sign, and date Part I of the DR/CAR form in Block 13. Return the DR/CAR form to the LA.

11. Issue the DR/CAR to the responsible organization within eleven working days of the post audit or surveillance closeout meeting, or discovery of an adverse or significant condition adverse to quality.

a. DR/CARs are issued separate from the audit/surveillance report or may be issued with the audit/surveillance report.

QAPM/LA 12. If the significant condition adverse to quality meets stop work criteria, issue a CAR within 5 working days after the determination that a stop work condition exists and process a stop work order (SWO) in parallel with the CAR according to PMP 16.04.

C. DR/CAR Distribution and Requesting Responses

LA 1. Under a cover letter signed by the QAPM, provide the responsible organization with Parts I and II of the DR/CAR form and the Part II Instruction sheet. Submit the letter and instructions through the responsible Program Support Organization (PSO) Technical Staff Personnel for NSNFP suppliers, when applicable. Include a request to perform the following actions:

LA

a. Complete the applicable blocks of the form and submit the response within 30 calendar days of the NSNFP QAPM-approved issuance date. If the need for an extension is anticipated, submit a request for an extension within 30 days of the issue date.

b. Submit the response, extension requests (if needed), and notification of completed remedial actions to prevent recurrence to the corrective action coordinator (CAC).

c. Complete all corrective actions within 60 calendar days of acceptance of proposed corrective actions.

D. Items Corrected During an Audit or Surveillance

LA/Auditor

1. When a condition adverse to quality is corrected during the audit (CDA) or surveillance and is verified as isolated by a certified auditor, complete Part I of Form 16.02-1, Blocks 1 through 10. Identify the corrective actions completed and verified under Block 11. Print name, sign and date in Block 12 (signature by the QAPM is not required).

2. Complete Blocks 24 (subject code) and 25 (direct cause code) of Part III on the DR/CAR form. All blocks not applicable should contain "NA" to designate not applicable.

3. Process the CDA according to Section VII, Records.

4. Enter data into CATTS. When performing data entry, fill in the date block under Part I Block 13 and Part III Block 28 under "QAPM" signature date. (These actions are necessary to reflect duration and closure in the database.)

E. DR/CAR Response, Extent of Condition, Remedial Action, and Action to Prevent Recurrence

Responsible Organization

1. Evaluate the adverse condition or the significant condition adverse to quality. Determine the extent and impact of the adverse condition on completed and ongoing work activities, and the extent and impact of the adverse condition on QA requirements, implementing documents, or both. Document the evaluation in Block 15 on Part II of the DR/CAR form.

   a. Based on the above evaluation, develop the proposed remedial corrective action (if applicable) and document the actions on Part II of the DR/CAR form.

2. For significant conditions adverse to quality, perform the following additional steps:

Responsible Organization

a. Determine the root cause(s) of the significant condition adverse to quality by using a formal root cause analysis method, such as:

(1) Barrier analysis

(2) Taproot

(3) Management oversight and risk tree (MORT)

(4) Kepner Trego.

This list is not all-inclusive. Commercially available root cause analysis methods are acceptable for use.

b. Ensure that individuals performing the root cause analysis have been trained and qualified in the analysis method used.

c. Ensure that root cause analysis documentation includes the identification of the method used, analysis, results, names, titles, and signatures of the individuals who performed the analysis.

d. Ensure that the analysis clearly describes the significant condition adverse to quality and adequately describes the root cause(s) to support the identification of corrective actions.

e. Submit the root cause analysis documentation with the CAR response.

3. For all DR/CAR reports, identify and document on the DR/CAR form a proposed completion date for the remedial action/action to prevent recurrence, and the name of the individual responsible to ensure the remedial action/action to prevent recurrence is completed. Where there are multiple actions to be performed, list the proposed completion dates, responsible person, and organization for each action.

4. Complete appropriate sections of Part II of the DR/CAR form (Blocks 19, 20, and 21 apply only to CARs).

Responsible Personnel

5. Sign and date the DR/CAR form and transmit the response to the NSNFP CAC (Block 22).

6. If the response will not be submitted by the due date or if corrective action completion dates will not be met, submit an extension request with justification for the delay in responding or completing corrective action to the NSNFP CAC.

F. Evaluation of Responses to Deficiency Reports and Corrective Action Requests

LA

1. Evaluate proposed remedial actions to prevent recurrence within 7 working days after receipt of a response for the following items to ensure the identified condition adverse to quality or significant condition adverse to quality has been adequately addressed.

    a. The responsible organization has determined and documented the extent of the impact of the adverse condition on completed work, ongoing work activities, implementing documents, and QA requirements.

    b. The proposed remedial actions address correction of the cited adverse condition and resolve the impact and extent of the condition adverse to quality.

2. For significant conditions adverse to quality, also evaluate the proposed corrective action for the following items:

    a. The root cause is stated.

    b. Root cause analysis documentation includes the identification of the method used, analysis, results, and the names, titles, and signatures of the individuals who performed the analysis.

    c. The analysis clearly describes the significant condition adverse to quality, the root cause, and is adequately stated to support the identification of corrective actions.

    d. The proposed corrective actions address the cited significant adverse condition and resolve the root cause.

3. If the disposition to the DR/CAR is unacceptable, return the DR/CAR to the responsible organization with comments, requesting appropriate changes or additional justification to the disposition of the DR/CAR, and specify a response due date.

4. Distribute the DR/CAR review comments to the CAC for posting the status in CATTS. A new response due date will be tracked in CATTS.

5. Upon determining that the proposed remedial action and action to prevent recurrence (when applicable) is acceptable, evaluate the DR or CAR for subject and direct cause codes. Coordinate the assignment of subject and direct cause codes with the LA assigned to coordinate codes in the CATTS database.

LA

a. For CARs, assign the root cause code based on the identified root cause in the responsible organization's root cause analysis. Assign the subject code based on the primary QARD requirement violated by the DR/CAR. The direct cause and root cause codes are the codes listed in QAS 16.03. The direct cause code reflects the direct cause of a condition adverse to quality identified in the DR/CAR.

6. Sign and date Part III of the DR/CAR form under "Response Evaluation."

7. Forward a copy of Part III of the DR/CAR to the responsible organization and the CAC for input into CATTS.

CAC

8. When correspondence is received acknowledging that committed remedial action/actions to prevent recurrence are complete, distribute the correspondence to the assigned LA.

LA

9. When notified that the remedial/corrective actions are complete, verify the corrective action by audit, surveillance, or document review.

a. Schedule the verification within 30 calendar days of notification of completion of corrective actions by the responsible organization.

b. If schedule conflicts prevent scheduling verification within this time period, notify the QASM to establish a due date for completing verification of corrective action.

c. When audit or surveillance verifies corrective action, record the audit/surveillance number on the DR/CAR form (Part III).

d. If corrective action is verified by review of documentation, then identify the documents reviewed on the DR/CAR Part III (use an additional page if necessary) and attach a copy of the documents or pertinent excerpts from the documents to the DR/CAR as appropriate. Documents that are available in QA records do not need to be duplicated as attachments for exhibits of completed corrective action.

e. If verification finds that corrective action is not complete, document the actions that are not complete on the DR/CAR form (Part III), and list the actions that were found complete. Forward a copy of Part III to the responsible organization with a request to establish a new completion date.

10. Sign and date the DR/CAR signifying acceptance and closure. Prepare a transmittal memo to the responsible organization notifying them that the DR/CAR is closed and submit the DR/CAR with memo to the NSNFP QAPM.

QAPM 11. Review the completed DR/CAR and any supporting documentation. Sign the DR/CAR to approve and close it. Sign the transmittal memo and transmit a copy of it and the closed DR/CAR to the responsible organization with a copy to the LA and CAC.

a. If there is an associated SWO with the CAR, process the SWO in accordance with QAS 16.04.

b. After obtaining program/facility approvals on the SWO form, sign and date the CAR to approve and close it.

c. Sign the associated memo notifying the responsible organization, and transmit copies of the closed SWO and CAR to the responsible organization, LA, and CAC.

LA 12. When a DR/CAR is closed (Parts I, II, and III), compile the individual DR/CAR with supporting documentation (i.e., responses, evaluations, documentation to support verification of the remedial action/action to prevent recurrence, and approvals) to form a record package. Proceed to the "Records" section of this procedure for transmitting records to the NSNFP Document Control Coordinator.

G. Delinquency Identification and Actions

CAC 1. Monitor due dates in the CATTS database and identify delinquencies.

2. Submit e-mail to the responsible organization management informing them of a delinquency for the following occurrences.

a. A response to a DR/CAR (DR/CAR Part II) is not received by the response due date.

b. Remedial action and action to prevent recurrence completion date is reached without notification from the responsible organization that the actions are complete.

3. Request the responsible organization manager submit a DR/CAR Part II response, provide notification that remedial action and action to prevent recurrence is complete, or request an extension for the applicable action with a justification for the extension. Include the assigned LA and the NSNFP QAPM on distribution of the e-mail. For NSNFP suppliers, submit the e-mail to the responsible procurement agent or project manager.

4. If a response has not been received within 10 working days of the e-mail requesting action, submit an e-mail to the assigned LA, requesting contact be made with the responsible organization management to expedite a response or establish a new due date.

a. Update the CATTS comment field to reflect the actions performed.

CAC 5. Contact the responsible organization management, requesting them to expedite a response or establish a new due date with justification.

6. If there is no response after 10 working days, submit an e-mail to the NSNFP QAPM and QASM informing them of the continued delinquency.

QAPM 7. As appropriate, prepare a memorandum to escalate the DR/CAR to the appropriate DOE level of management requesting assistance in obtaining a response from the responsible organization management.

CAC 8. When a response or correspondence is received, enter the response-received date in CATTS and distribute the response to the assigned LA.

a. If the assigned LA is unable to respond within the 7-day time frame (on travel, personnel leave, etc.), e-mail the QASM and inform him/her that the assigned LA is not available and request further direction.

QASM 9. If the assigned LA is not available, reassign a LA for evaluation or approve an extension for the evaluation by listing a new due date on an e-mail. Forward the e-mail to the CAC and responsible LA.

LA 10. Evaluate requests for extension. Provide an e-mail response to the responsible organization manager, CAC, and NSNFP QAPM with the results of the evaluation.

H. Corrective Action Tracking Trending System

QA Staff/ CAC 1. Provide CATTS status report of open DR/CARs via e-mail to the LAs, NSNFP QAPM, and the Manager, NSNFP on a bimonthly basis, or upon request.

2. Maintain due dates and action descriptions in the appropriate database fields. Annotate information in comment fields as appropriate.

3. The assigned LA is responsible for the accuracy and completeness of CATTS entries.

I. Handling of SWOs

LA 1. If an associated SWO is processed according to PMP 16.04, collect the closed SWO with all supporting documentation, assemble the records with the associated CAR records package, and transmit with the completed CAR records package in accordance with PMP 17.01.

IV. REFERENCES

DOE/SNF/MTX-001, The National Spent Nuclear Fuel Program QARD Requirements Matrix, current revision.

V. DEFINITIONS

Terms appearing in italics followed by the notation "see glossary" are defined in the NSNFP Documents Manual Introduction and Glossary.

VI. ATTACHMENTS

None.

VII. RECORDS

The following records generated as a result of this procedure require retention in accordance with the identified classification and PMP 17.01.

Lifetime

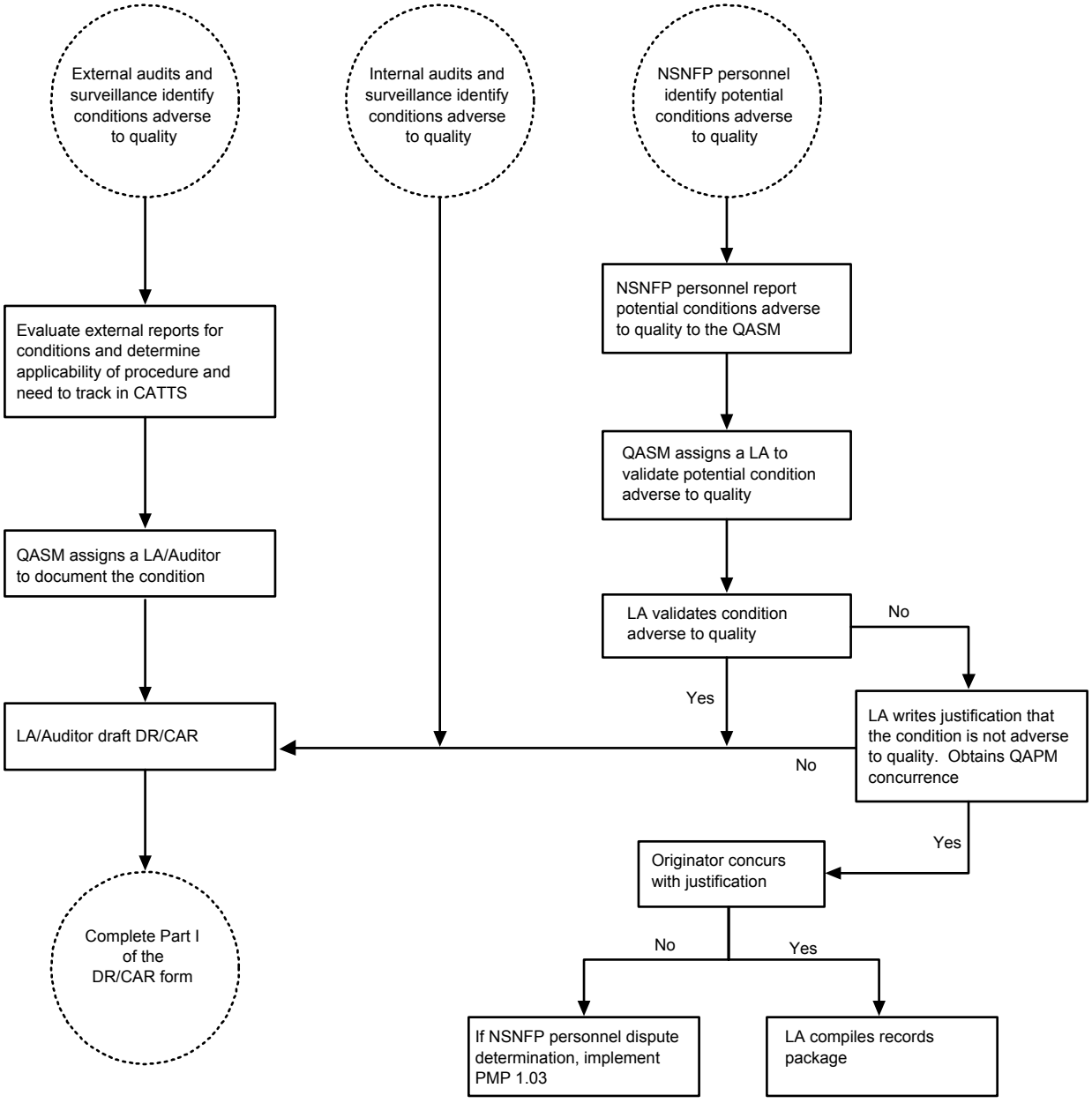
A. DR/CAR closed quality record package.

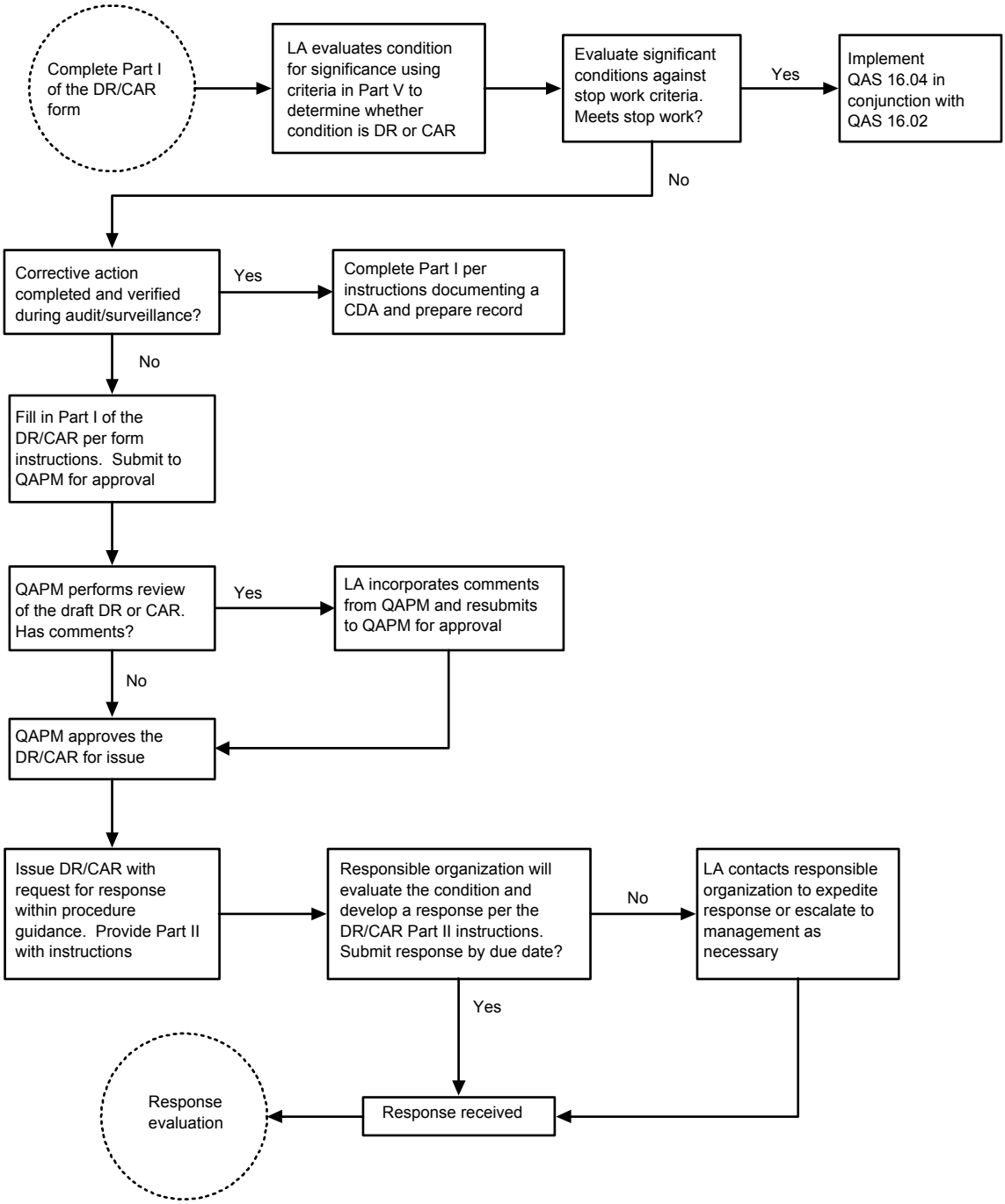
B. CDA forms (DR/CAR form Parts I and III documenting a CDA) and supportive documentation, as appropriate.

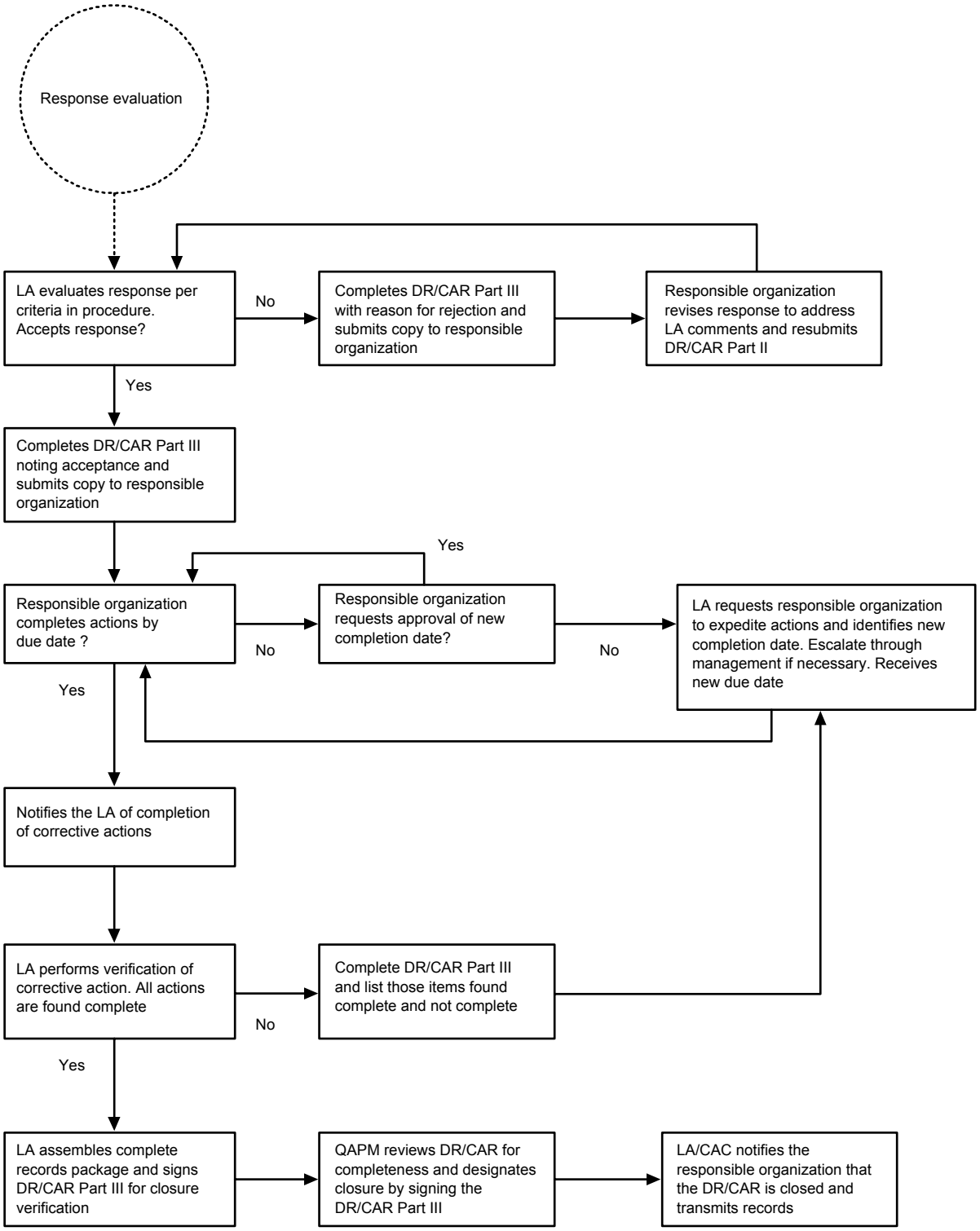
Nonpermanent

A. Documentation listing the potential condition adverse to quality and justification of why the condition is not adverse to quality and all supporting documentation.

VIII. PROCEDURE FLOW DIAGRAM




Complete Part I of the DR/CAR form
LA evaluates condition for significance using criteria in Part V to determine whether condition is DR or CAR
Evaluate significant conditions against stop work criteria. Meets stop work?
Yes
Implement QAS 16.04 in conjunction with QAS 16.02
No
Corrective action completed and verified during audit/surveillance?
Yes
Complete Part I per instructions documenting a CDA and prepare record
No
Fill in Part I of the DR/CAR per form instructions. Submit to QAPM for approval
QAPM performs review of the draft DR or CAR. Has comments?
Yes
LA incorporates comments from QAPM and resubmits to QAPM for approval
No
QAPM approves the DR/CAR for issue
Issue DR/CAR with request for response within procedure guidance. Provide Part II with instructions
Responsible organization will evaluate the condition and develop a response per the DR/CAR Part II instructions. Submit response by due date?
No
LA contacts responsible organization to expedite response or escalate to management as necessary
Yes
Response evaluation
Response received


Response evaluation
LA evaluates response per criteria in procedure. Accepts response?
No
Completes DR/CAR Part III with reason for rejection and submits copy to responsible organization
Responsible organization revises response to address LA comments and resubmits DR/CAR Part II
Yes
Completes DR/CAR Part III noting acceptance and submits copy to responsible organization
Yes
Responsible organization completes actions by due date ?
No
Responsible organization requests approval of new completion date?
No
LA requests responsible organization to expedite actions and identifies new completion date. Escalate through management if necessary. Receives new due date
Yes
Notifies the LA of completion of corrective actions
LA performs verification of corrective action. All actions are found complete
No
Complete DR/CAR Part III and list those items found complete and not complete
Yes
LA assembles complete records package and signs DR/CAR Part III for closure verification
QAPM reviews DR/CAR for completeness and designates closure by signing the DR/CAR Part III
LA/CAC notifies the responsible organization that the DR/CAR is closed and transmits records